

**ALASKA MEDICAID
PHARMACY AND THERAPEUTICS COMMITTEE**

**Location of Meeting
Frontier Building, 3601 C Street, Room 890/896**

**DRAFT MINUTES OF MEETING
January 22, 2010
8:00 a.m.**

Committee Members Present:

Marvin Bergeson, MD
Amber L. Briggs, Pharm.D.
Richard E. Brodsky, MD
Robert H. Carlson, MD (telephonic)
Daniel P. Kiley, DDS, MPH
Diane Liljegren, MD (telephonic)
Andrzej Maciejewski, MD
Paul Michaud, Pharm.D.
Claudia Phillips, MD
Jill Reid, R.Ph. (telephonic)
Sherrie D. Richey, MD
Janice L. Stables, MSN, ANP
Trish White, R.Ph.

Committee Members Absent:

Dharma V. Begich, Pharm.D
Jeffrey G. Demain, MD
Vincent Greear, R.Ph.

Others Present:

David Campana, R.Ph.
Melinda Sater, Pharm.D., First Health
Alex Malter, MD, MPH, Medical Director (telephonic)
Chad Hope, Pharm.D.
Flora Solomon

1. Call to Order – Chair

The meeting was called to order at 8:00 a.m.

2. Roll Call

A quorum was present.

3. Public Comment – Local Public / Health Practitioners

PAT NOLAN: Noted that he was speaking independently. He discussed several drugs that he felt should be on the PDL: Byetta, Actos, Lantus, and Levemir.

4. Re-Review of Benzoyl Peroxide/Clindamycin Combos (Red Category)

MATT JOHNSON: A representative of Sanofi-Aventis discussed BenzaClin topical gel, which is indicated for the treatment of acne vulgaris. BenzaClin has been the most prescribed and refilled branded product for acne since it was launched 10 years ago. It is effective as a single agent in treating acne and the pathogenic triggers of acne. It has rapid efficacy and visible results within two weeks,

which drives patient compliance. If patients do not see quick results, they become discouraged, stop treatment, and return to their doctor, resulting in increased doctor visits. BenzaClin was studied in more than 700 patients and has an excellent safety profile. In our original clinical trials, only one patient dropped out due to adverse events. We reduced the total lesion count by 63 percent over a 10-week period. We also reduced the bacterium that causes acne by 99.9 percent in the first two weeks of use. BenzaClin is offered in a 50-gram pump and a BenzaClin Care Kit, which was described. The cold and windy weather in Alaska causes dry skin. Treatment of acne with topical agents is difficult, because their main ingredient also causes dryness. BenzaClin helps battle dryness, resulting in patients being more compliant with their acne regiment. Many acne preparations contain alcohol, which also dries the skin, causing patients to become discouraged and stop treatment. BenzaClin is also dispensed in a convenient pump, which dispenses 99 percent of the product due to its unique vacuum system. BenzaClin should be included on the PDL, because it has demonstrated that it is an effective single agent in treating acne, patients and dermatologists prefer it, reduced callbacks, and it is simple to use.

Dr. Sater gave the First Health presentation on Benzoyl Peroxide/Clindamycin Combos. There is one available combination and three branded products: BenzaClin, Acanya, and Duac. Efficacy is enhanced by the combination therapy. They are useful for inflammatory lesions and have limited systemic absorption. The preferred agent is Duac. In December, there were 86 claims: 64% for BenzaClin, 18.6% for generic BenzaClin, and 17.4% for Duac. This was a green classification at the last review so there was no discussion. Since the last review, Acanya and generic BenzaClin have been added to the market.

DR. KILEY MOVED A CLASS EFFECT. SECONDED BY MS. STABLES. THE MOTION PASSED UNANIMOUSLY.

5. Re-Review of Topical Retinoids (Red Category)

There were no public testimonies.

Dr. Sater gave the First Health presentation on Topical Retinoids. There are three available chemical entities: Adapalene, Tretinoin, and Tazarotene. There are many branded and generic products. There is one combination product, Epiduo, which is new to the market. Mechanisms differ between the agents, but they are all effective for the treatment of acne. The adverse drug reaction profiles are similar for all the drugs. The preferred agents are generic Tretinoin, Differin, Tazorac, and Retin-A Micro. In December, there were 86 claims: 26.5% for Tretinoin, 19% for Differin, 19% for Epiduo, 13% for Evita (ph), 10% for Tazorac, 8.8% for Retin-A Micro, and less than 3% for Atralin. At the last review and without discussion, a motion for class effect passed unanimously. Since the last review, Epiduo has been added to this class.

DR. BRIGGS MOVED A CLASS EFFECT. SECONDED BY DR. KILEY. THE MOTION PASSED UNANIMOUSLY.

6. Review of Topical Anesthetics (Red Category)

There were no public testimonies.

Dr. Sater gave the First Health presentation on Topical Anesthetics. There is one available entity, the Lidoderm patch, which is indicated for the relief of pain associated with post-herpetic neuralgia. It is the only FDA approved treatment for PHN. The American Academy of Neurology recommends Lidocaine patches as one of several first line options for the treatment of PHN. Advantages over oral therapy include no first pass metabolism and minimal systemic exposure, which could potentially increase adherence to drug therapy and minimize side effects. Very little systemic absorption of Lidocaine occurs with the patches. Adverse drug reactions are mostly related to the topical route of administration. In December, there were 175 claims for Lidoderm, which cost \$48,000. This is a new class and no physicians wanted to discuss it.

DR. KILEY MOVED A CLASS EFFECT. SECONDED BY DR. BRIGGS. THE MOTION PASSED UNANIMOUSLY.

7. Review of Topical NSAIDS (Red Category)

There were no public testimonies.

Dr. Sater gave the First Health presentation on Topical NSAIDS. There is one available chemical entity, Diclofenac, which is available in two products. Flector is a transdermal patch and Voltaren Gel is topical gel. Flector is indicated for the treatment of acute pain associated with sprains, strains, or contusions. Voltaren Gel is indicated for relief of pain of osteoarthritis of joints amenable to topical treatment such as the knees and the joints of the hands. Systemic absorption is minimal, because these are topically applied products. The adverse drug reactions are mostly related to topical administration. In December, there were 69 claims: 70% for Flector and 30% for Voltaren Gel. This is a new class and no physicians wanted to discuss it.

DR. KILEY MOVED A CLASS EFFECT WITH ONE GEL AND ONE PATCH FORMULATION BEING INCLUDED ON THE PDL. SECONDED BY DR. MACIEJEWSKI.

Dr. Kiley noted that the application of the patches was not suitable for all anatomical sites. Both drugs are effective, but cannot always be interchanged. Dr. Carlson noted that the medically necessary clause could be utilized.

THE MOTION FAILED WITH SEVEN OPPOSED.

DR. BRIGGS MOVED A CLASS EFFECT. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.

8. Re-review of Incretin Mimetics (Red Category)

DOUGLAS GELOWITZ: A representative of Bristol-Myers Squibb discussed Onglyza (Saxagliptin). Onglyza is the first type 2 diabetic agent to pass the FDA's strict new guidelines on cardiovascular risks. Onglyza has been found to improve glycemic control in adults with type II diabetes, but it has not been studied in children, adolescents, or in combination with insulin. We are currently conducting clinical trials with Onglyza in an insulin combo. It is indicated as monotherapy, initial combination therapy with Metformin, and is an add-on therapy to TZDs and SUs in type 2 diabetes. Several trials and their results were discussed. The safety profile showed the adverse effects

were similar to placebo and discontinuations were very low. The most commonly reported adverse effects included urinary tract infection, upper respiratory tract infection, and headache. Dosage recommendations were reviewed. We request that Onglyza be added to the PDL.

JESSE HONG: A representative of Amylin reviewed the updates to Byetta (Exenatide). The FDA approved an extended indication for Byetta as a standalone medication with monotherapy in October 2009. The patient can now begin Byetta after they are diagnosed and, along with diet and exercise, can improve glycemic control in adults with type 2 diabetes. This monotherapy indication was supported by a clinical study, which was reviewed. The FDA also approved changes to Byetta's prescribing information to incorporate updated safety information, which was reviewed. In December 2009, the American College of Clinical Endocrinology updated their treatment algorithm and is now recommending GLP-1 agonists, because of its hypoglycemic minimization and weight loss benefits ahead of other oral agents when it comes to duo and triple therapies. Byetta is currently the only GLP-1 agonist in the marketplace.

ESTHER PEK: A representative of Merck discussed Januvia (Sitagliptin) and Janumet (Sitagliptin/Metformin). Sitagliptin was a first DPP-4 inhibitor licensed in the U.S. in 2003. There have been 7 million prescriptions to date. Sitagliptin should not be confused with incretin mimetics or analogs. It is an oral agent belonging to the class of DPP-4 inhibitors. Sitagliptin is indicated as a monotherapy; or in combination with Metformin, TZDs and sulfonylurea; or in triple combination with Metformin and sulfonylurea, in patients with type 2 diabetes. Several studies and their outcomes were reviewed. Januvia and Janumet should be retained on the PDL.

Dr. Sater gave the First Health presentation on Incretin Mimetics. There are four distinct entities in this class and one combination product. Two products are injections and two are oral. Mechanisms are slightly different impacting amylin secretion, incretin hormone stimulation, and dipeptidyl peptidase-4 inhibition. The summary of indications and FDA approved combinations are in the packet. None of the products is listed as first line agents in the 2009 update of the ADA Consensus Algorithm. In December, there were 131 claims. Among the DPP-4 inhibitors, Januvia had 100 percent of the market share. There was 1 claim for Symlin, 15 claims for Byetta, and 13 claims for Janumet. At the last review, there was limited discussion on the necessity of having all tools available to treat diabetes. A motion to prefer all drugs passed unanimously. Since the last review, Onglyza has been added to the market and there have been new warnings about Byetta and renal failure. No physicians wanted to discuss this classification.

In response to Dr. Briggs, Mr. Campana said Byetta was on a step-edit where patients had to have Metformin or a sulfonylurea before Byetta could be prescribed.

In response to Dr. Brodsky, Dr. Sater reviewed the drugs in the class. DPP-4 inhibitors include Januvia and Onglyza. There is one amylin analog, Symlin; one GLP-1 receptor antagonist, Byetta; and one combination DPP-4 inhibitor with Metformin, Janumet.

Dr. Maciejewski said he used all of the drugs in this class and they differed significantly in many aspects. Onglyza seems to have an interesting benefit in cardiovascular risk reductions.

DR. MACIEJEWSKI MOVED TO PREFER ALL AGENTS ON THE PDL.

The motion failed due to lack of a second.

DR. BERGESON MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES, WITH ONE DRUG FROM EACH CLASS BEING INCLUDED ON THE PDL. SECONDED BY DR. BRIGGS. THE MOTION PASSED UNANIMOUSLY.

9. Re-review of Ulcerative Colitis – Oral (Blue Category)

Dr. Sater gave the First Health presentation on Ulcerative Colitis. There are five chemical entities in this class with many different products. All of the drugs are metabolized in some way to 5-ASA. There are extended and immediate formulations. The indications vary among the agents, but they are all effective for the treatment of ulcerative colitis. The pill burden and the dosing regimens are more attractive for the delayed release forms. The preferred agents are Asacol, Sulfasalazine, and Pentasa. In December, there were 72 claims: 40% for Asacol, 36% for Sulfasalazine branded, 9.7% for Sulfasalazine, 8.3% for Pentasa, 2.8% for Balsalazide, 1.4% for Colazal, and 1.4% for Lialda. At the last review and without discussion, a motion stating all agents are therapeutic alternatives, but to include one Sulfasalazine and one delayed release product, passed unanimously. There is no new information in this class and no physicians wanted to discuss it.

DR. KILEY MOVED THAT ALL AGENTS WERE THERAPEUTIC ALTERNATIVES, BUT ONE SULFASALAZINE AND ONE DELAYED RELEASE PRODUCT SHOULD BE INCLUDED ON THE PDL. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

10. Re-Review of Opioids – ARBs (Blue Category)

JON BEATY: A representative of Boehringer Ingelheim discussed Micardis (Telmisartan) and Twynsta, a new combination of Telmisartan and Amlodipine. Micardis is indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive agents. New to the Micardis label is an indication for reducing risks for myocardial infarction, stroke or death from CV events in patients 55 years of age or older who are at high risk for developing major CV events and are unable to take ACE inhibitors. Several studies and their outcomes were reviewed. For cardiovascular risk reduction, the recommended dose of Micardis tablets is 80mg per day and can be administered with or without food. The use of Telmisartan with an ACE inhibitor is not recommended. Twynsta, a new combination of Telmisartan and Amlodipine, is indicated for the treatment of hypertension alone, or with or without other antihypertensive agents. Twynsta tablets may also be used as initial therapy in patients who are likely to need multiple drugs to achieve their blood pressure goals. The normal starting dosage for Twynsta is Telmisartan 40mg plus Amlodipine 5mg, once daily. Patients requiring larger blood pressure reductions may be started on Twynsta 80mg plus 5mg, once daily. Initial therapy with Twynsta is not recommended in patients greater than 75 years of age or with hepatic impairment. Several studies and their outcomes were reviewed.

FRED AMBURGER: A representative of Novartis discussed Valtorna, a combination of Aliskiren and Valsartan. Valtorna is the first and only FDA approved antihypertensive therapy to target two key points within the renin system. It is indicated for the treatment of high blood pressure in patients not adequately controlled on Aliskiren or an angiotensin receptor blocker as monotherapy, and also as an initial therapy in patients likely to need multiple drugs to achieve their blood pressure goals. Valtorna

combines Valsartan, the active ingredient in Diovan, and Aliskiren, the active ingredient in Tekturna. A study and its outcome was reviewed. Valtorna, at maximum recommended doses, provides significantly greater reductions in blood pressure than does monotherapy with either agent in patients with hypertension. The tolerability profile is similar to that of Aliskiren and Valsartan alone.

Dr. Sater gave the First Health presentation on ARBs. There are seven available individual products in this class. The indications vary by product, but clinically all drugs are used for all indications. They have similar pharmacokinetic profiles and clinical efficacy. All the drugs have combination products with hydrochlorothiazide; a couple of them have combination products with Amlodipine and one has a combination product with Aliskiren. The preferred agents are Diovan, Cozaar, Micardis, Benicar and Avapro. In December, there were 833 claims, including the combinations. For the individual agents, there were 613 claims: 37% for Diovan, 26% for Cozaar, 16.3% for Micardis, 10% for Benicar, 8.2% for Avapro, and less than 1% for Atacand and Teveten. For combination products, there were 220 claims: 57.3% for Diovan HCT, 14.6% for Hyzaar, 12.7% for Benicar HCT, 10.5% for Avalide, 4% for Micardis HCT, and less than 1% for Teveten HCT. Last year, this was a green class. Without discussion, a motion to declare a class effect carried with one opposed.

MS. STABLES MOVED A CLASS EFFECT. SECONDED BY DR. BRIGGS.

Mr. Campana explained the policy on the combination products. If the main ingredient is preferred and it is cost effective, the combination product will be preferred.

THE MOTION PASSED UNANIMOUSLY.

11. Re-review of Oral Beta-Blockers (Blue Category)

There were no public testimonies.

Dr. Sater gave the First Health presentation on Oral Beta-Blockers. There are 15 available entities in this class. The indications vary between the agents. Carvedilol and Labetalol have alpha-1 receptor activity. Nebivolol has a nitric oxide pathway activity. Carvedilol and Toprol XL are indicated for heart failure, but other beta-1 selective agents are used. In 2009, the American College of Cardiology and the American Heart Association Guidelines recommended beta-blockers for stages B and C heart failure, specifically mentioning Bisoprolol, Carvedilol, or Metoprolol Succinate in stage C. In December, there were 2,043 claims: 32% for Atenolol, 16.5% for Metoprolol Succinate, 12.7% for Metoprolol Tartrate, 10.8% for Propranolol, 10.2% for Carvedilol, 4% for extended release Propranolol, and less than 12% for all the rest. Last year there was a significant discussion regarding the safety of Atenolol. The motion to non-prefer Atenolol, but grandfather it to allow patients currently using it to continue using it, to send out an educational letter to prescribers outlining concerns of the use of Atenolol in hypertension, and retain Carvedilol and add Nebivolol on the PDL passed with three opposed.

In response to Dr. Brodsky, Dr. Sater said there has been no new information on Atenolol this year.

Dr. Brodsky discussed the fact different agents were used for different indications: Atenolol is used for hypertension; Carvedilol and other drugs are used for heart failure.

Dr. Maciejewski talked about his recommendations last year on Atenolol. I have discussed this issue with cardiology researchers who were pleasantly surprised that Atenolol was excluded from our PDL, which no other PDLs in the nation have done. There is no new information on Atenolol; therefore, I extend the same recommendation this year.

In response to Dr. Richey, Dr. Sater reviewed the currently preferred drugs and noted that Atenolol was no longer preferred.

Dr. Richey said Labetalol was the preferred drug for pregnant women.

Mr. Campana noted that Labetalol was generically available and would likely be included on the PDL.

DR. PHILLIPS MOVED TO NON-PREFER ATENOLOL, BUT GRANDFATHER IT FOR PATIENTS CURRENTLY USING IT, AND RETAIN CARVEDILOL AND ADD NEBIVOLOL TO THE PDL, AND A CLASS EFFECT FOR THE REMAINDER OF THE AGENTS. SECONDED BY DR. MACIEJEWSKI.

Dr. Briggs did not feel it was necessary to prefer Bystolic. Dr. Maciejewski said Bystolic had a different mechanism of action and he recommended including it on the PDL.

THE MOTION PASSED WITH ONE OPPOSED.

12. Re-review Insulins (Blue Category)

STEVE CHANG: A representative of Eli-Lilly discussed Humulin and Humalog. The study published in Diabetes Care in June 2009, which included Humalog and Humulin, was reviewed. The committee should consider the unique insulin options that Eli-Lilly provides for patients. Full prescribing information can be provided upon request.

CHRIS HANSON: A representative of Novo Nordisk discussed Novolog's new label indication. For pump patients, Novolog can now be left in the reservoir for six days. The basis for this new indication was reviewed. Patients who are pumping can now change the reservoir every six days instead of every three days, but they still need to change their infusion sets. We ask that the PDL be maintained as it currently exists.

Dr. Sater gave the First Health presentation on Insulins. There are six sub-groups of insulins for consideration. There are three recombinant DNA types and three biosynthetic analog types: short, intermediate, and pre-mixed combos in the recombinant DNA group; and rapid, long and pre-mixed combos in the biosynthetic analog group. For all insulins, there were 702 claims in December. For the long-acting biosynthetic analog type, there were 352 claims: 65% for Lantus vials, 28.4% for Lantus Solostar (ph), 6 for Lantus cartridges, and the rest were for Levemir. For the rapid acting insulins, there were 237 claims: 37.6% for Novolog vials, 29.1% for Novolog pens, 17.3% for Humalog vials, 9.2% for Humalog pens, 3.4% for Novolog cartridges, 2.53% for Apidra vials, and less than 1% for Humalog cartridges. In the biosynthetic pre-mixed category, there were 29 claims: 58.6% for Novolog 70/30, 10.3% for Humalog 75/25, 10.3% for Humalog 70/30, 7% for Humalog 50/50 pens, 7% for Humalog 50/50 vials, and 7% for Humalog 75/20. There were 20 claims for 70/30 insulin: 80% for Novolin and the rest for Humulin vials or pens. There were 40 claims for insulin N: 75% for Novolin

N and 25% for Humulin N. In the insulin R category, there were 24 claims: 66.7% for Novolin R and 33.3% for Humulin R. At the last review, there was discussion on the long-acting insulins. There was a significant discussion of the grandfather clause for insulins and the importance of brand stability. Each subclass was considered separately and the need for a product in each class was agreed upon. The motion for a class effect in each distinct subclass, and a grandfather clause for patients currently using Lantus, carried with one opposed. Since the last review, Apidra has a pediatric indication for children down to age 1. The currently preferred agents are all the Novo Nordisk products, Lantus and Levemir.

In response to Dr. Richey, Dr. Sater said Lantus and Levemir pens were not preferred, but the remainder of the pens in the class was preferred.

In response to Dr. Brodsky, Dr. Sater said no physicians wanted to discuss this class this year. Historically, the only thing that people felt strong about was the Lantus versus Levemir issue.

DR. KILEY MOVED A CLASS EFFECT IN EACH DISTINCT SUBCLASS, A GRANDFATHER CLAUSE BE ADDED FOR PATIENTS CURRENTLY USING LANTUS IF LANTUS WAS NOT PREFERRED.

Dr. Richey noted the only drug in this class used for pregnant women for long periods of time was Lantus. The grandfather clause would not apply to new pregnancy patients. She suggested amending the motion to prefer Lantus.

DR. KILEY AMENDED THE MOTION TO INCLUDE LANTUS ON THE PDL. SECONDED BY DR. RICHEY.

THE AMENDMENT TO THE MOTION PASSED UNANIMOUSLY.

THE MOTION, AS AMENDED, PASSED UNANIMOUSLY.

13. Re-review of TZDs (Blue Category)

ROBERT PEARSON: A representative of GlaxoSmithKline discussed Avandia. Two new trials and their outcomes were reviewed. With many medications to choose from for the management of diabetes, it is reassuring to know that Avandia is now the most well studied, oral anti-diabetic medication with over 1.9 million patient years of clinical trial data ranging from pre-diabetes to later stage diabetes. Avandia is also the only TZD with a cardiovascular outcomes trial that met its primary endpoint. Only Avandia has been proven to sustain glycemic control for up to five years. The American Association of Clinical Endocrinologists published their updated diabetes treatment algorithm, which reaffirms the use of Avandia as monotherapy or combination therapy for the treatment of type II diabetes. Due to its solid efficacy profile, Avandia should remain a preferred product on the PDL.

Dr. Sater gave the First Health presentation on TZDs. There are two TZDs currently available: Rosiglitazone and Pioglitazone. Both are available in combination with Metformin and Glimepiride. The individual products are approved as an adjunct to diet and exercise to lower blood glucose concentrations in patients with type II diabetes. The combinations are approved as an adjunct to diet and exercise for patients already stable on the agents or for patients who have had inadequate response

with either agent alone. In 2009, the ADA updated its treatment algorithm and recommended Actos as a tier two intervention, but Avandia is not listed as a tier one or tier two intervention. In December, there were 403 claims. For the single agents, there were 389 claims: 87% for Actos. All the agents, including all the combinations, are preferred on the PDL. For the TZD/Metformin, combinations there were 12 claims: 6 each for Actos, plus Met and Avandamet. In the TZD/Sulfonylurea combinations there were 2 claims for Avandaryl. At the last review and without discussion, a motion for a class effect passed unanimously. Since the last review, the ADA updated its treatment algorithm and a long-term study of Avandia was released. The RECORD trial showed no increased risk of cardiovascular death or hospitalization, but did show a slight increased risk of heart failure compared with Metformin and Sulfonylureas.

DR. KILEY MOVED THE DRUGS IN THIS CLASS WERE THERAPEUTIC ALTERNATIVES WITH NO PREFERENCES EXPRESSED. SECONDED BY DR. MACIEJEWSKI.

Dr. Briggs noted that the 2009 ADA algorithm does not recommend the use of Rosiglitazone.

THE MOTION PASSED WITH THREE OPPOSED.

Break from 9:25 a.m. to 9:48 a.m.

14. Re-review of Sulfonylureas (Green Category)

Dr. Sater gave the First Health presentation on Sulfonylureas. There are three available entities and several different preparations. There is no new information in this class. Every generic product is preferred. In December, there were 478 claims: 37.7% for Glyburide, 21.1% for Glipizide, 19.3% for Glimepiride, 18.2% for Glipizide ER, and less than 5% for the rest. At the last review, there was discussion centered on the need for both immediate and extended release products, because there are subtle differences between agents. A motion for a class effect, including one Glipizide product, passed with one opposed.

In response to Dr. Brodsky, Dr. Sater said it has been historically stated that Glipizide is better for elderly patients as it causes less hypoglycemia and renal failure.

Dr. Richey noted that Glyburide was the only oral hyperglycemic that has been well studied in pregnancy for the treatment of gestational diabetes.

Dr. Sater said as a rule, long-standing generic drugs were rarely excluded from the PDL. Newer generics, even out to 18 months, are sometimes excluded due to their prices.

DR. KILEY MOVED THE DRUGS IN THIS CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY MS. STABLES. THE MOTION PASSED WITH ONE ABSTENTION.

15. Re-review of Biguanides (Green Category)

Dr. Sater gave the First Health presentation on Biguanides. There is one entity in this class, Metformin. There are several formulations including extended release, immediate release, and combinations with Glipizide, Glyburide and the TZDs. Metformin is FDA approved in combination with sulfonylureas or insulin to improve glycemic control in adults greater than 17 years of age. There is no new information in this class. The preferred agents are Metformin immediate release and Metformin extended release. In December, there were 1,049 claims: 84% for immediate release Metformin and 14.8% for extended release Metformin. At the last review and without discussion, a motion to include both immediate release and extended release Metformin passed unanimously.

DR. RICHEY MOVED TO INCLUDE BOTH IMMEDIATE RELEASE AND EXTENDED RELEASE METFORMIN ON THE PDL. SECONDED BY DR. BRIGGS. THE MOTION PASSED UNANIMOUSLY.

16. Re-review of Meglitinides (Green Category)

Dr. Sater gave the First Health presentation on Meglitinides. There are two available agents: Repaglinide and Nateglinide. There is no new information in this class. The preferred products are Starlix and Prandin. In December, there were 9 claims: 77.8% for Starlix and 2 for Prandin. At the last review and without discussion, a motion for class effect passed unanimously.

DR. BRIGGS MOVED A CLASS EFFECT. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

17. Re-review ACE Inhibitors (Green Category)

Dr. Sater gave the First Health presentation on ACE Inhibitors. There are 10 available products. Most of them are available with combinations of hydrochlorothiazide. There is no new information in this class. The preferred agents are Lisinopril, Enalapril, Benazepril, Captopril, and their corresponding hydrochlorothiazide combinations. In December, there were 1,896 claims: over 1,500 for Lisinopril, 170 for Lisinopril with hydrochlorothiazide, and less than 10% the remainder of the agents. At the last review and without discussion, a motion for class effect, and to preferentially include Lisinopril, passed unanimously.

DR. MACIEJEWSKI MOVED A CLASS EFFECT, AND TO PREFERENTIALLY INCLUDE LISINOPRIL, ON THE PDL. SECONDED BY MS. STABLES. THE MOTION PASSED UNANIMOUSLY.

18. Re-review of Alpha Glucosidase Inhibitors (Green Category)

Dr. Sater gave the First Health presentation on Alpha Glucosidase Inhibitors. There are two available products. No new information on this class, except that generic Precose was added to the market. The preferred agent is branded Precose. In December, there were 8 claims: 5 for branded Precose and 3 for generic Precose. At the last review and without discussion, a motion for class effect passed unanimously.

DR. BRIGGS MOVED A CLASS EFFECT. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

19. Re-review of Renin Inhibitors (Green Category)

Dr. Sater gave the First Health presentation on Renin Inhibitors. There is one chemical entity in this class, Aliskiren, with two available combination products. There is no new information in this class. The preferred agents are Tekturna and Tekturna HCT. In December, there were 42 claims: 39 for Tekturna. At the last review and without discussion, the motion for class effect passed unanimously.

DR. BRIGGS MOVED A CLASS EFFECT. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

20. Re-review of Calcium Channel Blockers (Green Category)

Dr. Sater gave the First Health presentation on Calcium Channel Blockers. There are nine agents in this class available in combinations with ACE inhibitors, ARBs and Atorvastatin. A few new agents have been added to the market, which were reviewed. The preferred Dihydropyridines are Amlodipine, Nifedipine ER, Felodipine ER, Nifedipine immediate release, Nifedical XL, Afeditab CR, Nifedipine SA, and Nifediac CC. In December, there were 987 claims. For the Dihydropyridines, there were 628 claims: 85.7% for Amlodipine and 12% for the remainder. The preferred Nondihydropyridines are Diltiazem CD, Verapamil, Diltiazem ER, Diltiazem XR, Diltiazem immediate release, and Diltiazem SR. For Nondihydropyridines, there were 209 claims: 39% for Diltiazem CD, 31.6% for Verapamil, 14.8% for Diltiazem ER, and less than 10% for the rest. There is no new information in this class. Lotrel is the preferred product for the combination products. There were 55 claims for combinations: 54.6% for Lotrel, 43.6% for generic Lotrel, 1 for Tarka, 9 for Caduet, 25 for Xford (ph), and 1 for Xford (ph) HCT. At the last review, a motion for class effect when treating hypertension, including at least one Amlodipine, one Verapamil, and one Diltiazem product passed unanimously.

DR. KILEY MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY MS. STABLES. THE MOTION PASSED UNANIMOUSLY.

21. Re-review of Immunosuppressants (Green Category)

Dr. Sater gave the First Health presentation on Immunosuppressants. There are five available chemical entities with seven available products. Cyclosporine and Mycophenolate are available as different salts, but the products are not interchangeable, nor are any of these drugs. There is no new information in this class. Every agent is preferred. In December, there were 95 claims: 25% for Prograf, 21% for Azathioprine, 17.9% for Mycophenolate Mofetil, 7.4% for Myfortic, 7.4% for Gengraf, 6.3% for Neoral, 4.2% for Rapamune, 4.2% for Tacrolimus, 3.2% for CellCept, and 3.2% for Cyclosporin. At the last review and after a brief discussion, a motion stating all are therapeutic alternatives passed unanimously.

DR. BERGESON MOVED THE DRUGS IN THIS CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. BRIGGS. THE MOTION PASSED UNANIMOUSLY.

22. Re-review of Glaucoma Agents (Green Category)

Dr. Sater gave the First Health presentation on Glaucoma Agents. There are many available products, dosage forms, brands, generics, single entities and combinations in this class. This committee chose to consider all glaucoma agents as one group in previous years. In December, there were 67 claims: 6 for alpha-2 adrenergic agents, 11 for beta-blockers, and 3 for carbonic anhydrase inhibitors. The lion share was for the prostaglandin agents, all of which are preferred: 45% for Xalatan, 23% for Travatan, 21% for Travatan Z, and 11% for Lumigan. At the last review and without discussion, a motion stating all agents are therapeutic alternatives, in their respective subclasses, passed unanimously.

DR. BERGESON MOVED THAT ALL AGENTS ARE THERAPEUTIC ALTERNATIVES IN THEIR RESPECTIVE SUBCLASSES. SECONDED BY DR. BRIGGS. THE MOTION PASSED UNANIMOUSLY.

23. Re-review of Topical Immunomodulators (Green Category)

Dr. Sater gave the First Health presentation on Topical Immunomodulators. There are two available agents in this class. Both are currently preferred. There is no new information in this class. In December, there were 82 claims: 63% for Elidel and 37% for Protopic. At the last review and without discussion, a motion that both are therapeutic alternatives passed unanimously.

DR. BERGESON MOVED THE DRUGS IN THIS CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY MS. STABLES. THE MOTION PASSED UNANIMOUSLY.

24. Review Minutes from November 2009 Meeting

Mr. Campana reviewed the corrections to be made to the November 2009 meeting minutes.

DR. KILEY MOVED TO APPROVE THE NOVEMBER 2009 MEETING MINUTES AS CORRECTED. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.

25. Comments from Committee Members or Chair

Mr. Campana said the next meeting would be April 16, 2010, and listed of drugs to be reviewed.

The committee discussed the possibility of having a consent agenda for the green category. Information would be provided to the committee before the meeting and then the class could be approved with a single motion, unless a committee member wanted to make a change. Mr. Campana said a consent agenda could be discussed, but he thought it was nice to review the previous actions and utilization for each class during the meeting.

26. Adjourn

The meeting adjourned at 10:19 a.m.